



MEMORANDUM

Date: December 5, 2008

From: Alan Trounson, Ph.D., CIRM President

To: Independent Citizens Oversight Committee

Subject: Extraordinary Petition for Application RT1-01137

Enclosed is a letter from Mr. Jeffrey Janus and Mr. William B. Adams, of International Stem Cell Corporation, an applicant for funding under RFA 08-02, CIRM Tools and Technologies Awards. This letter was received at CIRM at least five working days prior to the December ICOC meeting, and we are forwarding it pursuant to the ICOC Policy Governing Extraordinary Petitions for ICOC Consideration of Applications for Funding.

As required by that policy, I have reviewed the petition (referencing reviewer comments and the submitted application as necessary) in consultation with Dr. Csete and the scientific staff, and concluded that the petition does not present compelling evidence that should alter the recommendation or score of the Grants Working Group (GWG). Briefly, we disagree with the suggestion that the application was not recommended for funding because of an “inherent bias toward academic applicants” and specifically a bias toward applicants with a large publication record. GWG reviewers were specifically instructed by CIRM staff to consider the industry achievements (successful project leadership and management) of industry applicants and not to consider peer-reviewed publications as a necessary part of the track record of industry applicants. Industry applicants have the opportunity to cite relevant industry accomplishments in the biosketch, but the PI did not take the opportunity. In the future, to give reviewers more information, the PI may want to take full advantage of the biosketch to cite appropriate credentials and accomplishments. CIRM staff will be prepared to provide further analysis, should that be requested by any member of the committee.

Redactions, if any, have been made pursuant to the policy, in consultation with the author(s) of the letter. An unredacted version will be available for review in closed session.

The enclosed letter represents the views of its author(s). CIRM assumes no responsibility for its accuracy.

In addition, a copy of the CIRM Review Summary for this application is provided for reference.



December 2, 2008

To Dr. Alan Trousen; Dr. Marie Csete; Mr. Steve Klein:

We would like to submit the following comments concerning our latest grant application RT1-01137-1.

We believe that the current CIRM grant application process contains a structural and unintentional bias that penalizes private industry applications, particularly those from smaller companies seeking new clinical applications, and favors academic applications conducting traditional basic research. This bias is mainly due to two fundamental differences between academia and industry, which are: (1) the weight given to the publication record of the PIs and (2) the weight given to prior peer-review of research results, both of which boil down to a reliance on the history of peer-reviewed publications by the applicant or its PI.

Using the three grant applications submitted by our company as examples, comments in the critiques of our grant applications RFA 07-04, RFA 07-05 and our latest grant application number RT1-01137-1 all call into question the track records of our PIs (three different PhDs that work full time for our company). We believe this is because their publication records are not documented in a manner that is expected and normally seen by our competitors in academia.

As a general rule, industry does not publish its results because of the proprietary nature of the developing technology. Expertise in a particular area is commonly earned through experience in that field, as opposed to formal academic study. In addition, it is a fundamental business necessity that companies keep all steps of the process private to maintain the patentability of the developing product and secure a potential niche in the marketplace. As a consequence, when a discovery is made in a small biotech company, such as is the case with our corneal construct (RT1-01137-1), it is unlikely that there will be a PI who is published and considered to be an expert in the field. In fact, the more groundbreaking the research by the PI; the less likely it will be to have been published prior to seeking a grant.

For example, the comment in the critique of our grant application (RT1-01137-1) that *“of greater concern, the PI did not include any biochemical or cell biological analysis to demonstrate the functional validity of the corneal constructs as surrogates for authentic cornea”* seems to us to be more a criticism that the biochemical or cell biological data provided was not substantiated by a peer-reviewed publication than that there was no data. In fact, the application did contain a significant amount of data and independent laboratory verification.

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For these reasons, we believe that it is inappropriately difficult for a privately owned company to successfully compete for grants under the current criteria, particularly if the data involved represents a discovery that has never before been achieved in the laboratory, as is the case with the self-assembling corneal construct for which we sought funding for further research.

While we can fully appreciate the need for proper documentation of experience, data validity and feasibility of the projects, we also request that you to look at the situation through the eyes of a person from Industry to help us resolve this disparity. When comparing grants from academia and industry, you really are comparing apples and oranges. Thus, for the grant process to ever be considered "fair", allowances need to be made so as to properly compare the apples (academia) to the oranges (industry).

Thank you for your consideration of our concerns.

Jeffrey Janus
President

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What Dr. Buz'Zard did not say is that prior to publishing it is imperative that industry file their patents. It is the royalties from those patents that will pay CIRM. I request time at the upcoming board meeting to express out position.

Thank you for your cooperation,

William B. Adams
Co-Founder and CFO